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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/840,143 | 05/06/2004 | Jayant Ekanth Khanolkar | 9626 | 7415 |

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| EXAMINER | |
|---|---|
| PALENIK, JEFFREY T | |
| ART UNIT | PAPER NUMBER |
| 1615 | |
| MAIL DATE | DELIVERY MODE |
| 05/07/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/840,143 | KHANOLKAR ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey T. Palenik | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application*

The Examiner thanks the Applicants for their timely reply filed on 5 December 2007, in the matter of 10/840,143. A response to the remarks and amendments are herein presented under 37 CFR § 1.113.

### *Response to Remarks*

The Examiner acknowledges Applicants' amendment to the Abstract and hereby **withdraws** the objection. The Examiner also notes the **withdrawal** to the priority objection, which was addressed telephonically on 30 December 2007.

The rejection under the *second paragraph* of *35 USC §112* made over the instant claim 11 is hereby **withdrawn** in view of Applicants' amendments. The rejection under the *first paragraph* of *35 USC §112* made over the instant claims 11-17 is hereby **withdrawn** in view of Applicants' arguments. Lastly, the *35 USC §102* rejection over Tanner et al. (USPN 5,569,466) is hereby **withdrawn** in view of Applicants' arguments.

### *New Grounds of Rejection*

Applicants have added no new claims. Claims 1-17 still represent all claims currently under consideration.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 7-11 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cuca et al. (USPN 5,002,777).

The instant independent claims 1 and 11 are drawn to a soft gel capsule composition and its preparation method, wherein the capsule comprises a high weight percentage (e.g. about 55% to about 90%) of a suspended pharmaceutical active, from about 0.001% to about 1.00% by weight of a stabilizing agent, and from about 9% to about 39% of a solvent. Dependent claims 2, 4 and 7, respectively further limit the active agent, stabilizing agent, and solvent of the composition to narrower percent ranges (e.g. about 58% to 80%, 0.01% to about 1.00%, and about 20% to about 39%, respectively). Claims 8, 9, 15 and 16 further limit the solvent to polyethylene glycol. Claims 10 and 17 recite that the composition further comprises from about 0.1% to about 5% by weight of water.

Cuca et al. teach in Example 1, a soft gel encapsulated antacid suspension formulation which contains about 66% calcium carbonate as the active agent, about 0.5% Carboxymethylcellulose sodium (CMC-Na) as the stabilizing agent and about 33% polyethylene glycol (PEG-400) as the solvent. Carboxymethylcellulose sodium is known and defined as a suspension stabilizer (Remington, pg. 45). Water is taught as part of the composition, the presence of which is further defined by claim 1 to be less than about 5% by weight of the

composition. The Example also teaches making the pourable fill composition as well as encapsulating it in a soft shell capsule.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wen et al. (USPN 6,001,392).

The instant independent claims are drawn to a soft gel capsule composition and its preparation method, as described above. Dependent claims 3 and 12 further limit the active agent of the composition to specific categories of drugs such as antitussives and analgesics. Claims 5, 6, 13 and 14 further limit the stabilizing agent to a disodium salt of ethylene diamine tetraacetic acid (e.g. disodium edetate).

Wen et al. teaches in claim 1, a sustained release composition whose coated portion

comprises 20-80% by weight of a suspended pharmaceutical active (e.g. a drug/resin complex). Said pharmaceutical may an antitussive such as dextromethorphan (claims 4 and 5) or another type such as an analgesic, an anti-inflammatory, or an antipyretic drug (claim 7). Stabilizing agents (e.g. preservatives) such as methylparaben and propylparaben are taught in formulation at 0.08% and 0.05%, respectively (Examples). Other preservatives such as disodium EDTA are taught as being functionally equivalent to the formulation (col. 7, lines 60-65). Polyethylene glycol and water are also taught in the formulation (Examples). Methods of preparation are taught in Example 1 and preparation of the composition as encapsulated liquid suspensions is taught (col. 6, lines 38-44).

Wen does not specifically teach disodium EDTA, polyethylene glycol or water, within the respective ranges as claimed by Applicants'. Since the values of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to be motivated to substitute in disodium EDTA as a functionally equivalent preservative to methyl- and/or propylparaben and still expect to successfully achieve the desired encapsulated pharmaceutically active suspension. It would have been equally customary for an artisan of ordinary skill to adjust the compositional percentages of all three components and in order achieve the desired encapsulated formulation. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

All claims have been rejected; no claims are allowed.

***Conclusion***

Due to the new grounds of rejection, this action is deemed **non-final**.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615